REMARKS/ARGUMENTS

In the Office Action mailed September 21, 2010, The Examiner has restricted the claims into fifteen groups, which are described below.

Group 1, claims 1-5, 7, and 22-23, drawn to a method for *in vitro* culturing of corneal endothelial cells;

Group 2, claim 6, drawn to a method of making ECM coated plates;

Group 3, claims 8-10, drawn to human corneal endothelial cells;

Group 4, claims 11-13, drawn to an apparatus for growing cells in culture coated with a mixture of BCE-ECM;

Group 5, claims 14-15, drawn to an apparatus for growing cells in culture coated with an artificial-ECM;

Group 6, claims 16-20 and 24, drawn to a method of making HCEC cells wherein said HCEC are lacking class I HLA antigens;

Group 7, claims 25-27, drawn to a cell depository comprising HCEC;

Group 8, claims 28-33, drawn to a method of producing a cell depository comprising HCEC;

Group 9, claims 34 and 39, drawn to a method of transporting HCEC for transplantation;

Group 10, claims 37-38, drawn to a method of transporting HCEC for transplantation;

Group 11, claim 40, drawn to a method for protecting the regenerated corneal button from denuding during transport or implantation;

Group 12, claim 43, drawn to a method of storing HCEC regenerated target tissue for transplantation;

Group 13, claims 44-49, drawn to a method for denuding a native cornea;

Group 14, claims 50 and 52-54, drawn to a reconstituted extracellular matrix preparation; and

Group 15, claims 55-56, drawn to a method of coating a denuded cornea.

The Examiner contends that there fifteen groups of inventions, because the claims are directed to more than one species of a generic invention, and they do not relate to a single inventive concept, and so do not have unity of invention which could link all of the claims.

The Examiner considers the different types of ECM, surfaces, methods of use, target tissues, etc., to be distinct and would require multiple searches. In addition, the Examiner is requiring the election of a single species to whichever generic claim is elected. The generic claims are alleged to be claims 1-3, 6-11, 13-16, 19-21, 25-31, 34, 37-40, 43-50, and 55-56. Thus, Applicant would be required to elect a species of tissue source, growth factors and ECM when responding to the Restriction Requirement.

Applicant elects Group I, and elects, human corneal cells on artificial ECM coated plates, all with traverse.

Discussion of the Restriction Requirement

Applicant submits that the restriction requirement is improper for the reasons set forth below.

A. The Restriction Requirement Does Not Properly Consider the Generic Linking Claims

A restriction requirement must be based on the invention as claimed. As stated in the MPEP at Section 809.02: "Where only generic claims are presented, *no restriction can be required* except in those applications where the generic claims recite such a multiplicity of species that an unduly extensive and burdensome search is necessary" (emphasis added). The pending application contains several claims that are generic to and, thus, link two or more categories of subject matter set forth in the restriction requirement. For example, claim 1 is directed to a method of non-enzymatic harvesting and *in vitro* culturing corneal endothelial cells for transplantation. Accordingly, claim 1 encompasses and, thus, links the subject matter of each of Groups I-V, and XIV.

The Applicant is entitled to claim a genus. *Id.* Furthermore, the rules governing restriction requirements provide for such claims. For example, 37 C.F.R. § 1.141 provides that a reasonable number of species of an invention may be specifically claimed in different claims of an application provided the application also includes an allowable claim generic to all of the claimed species and all of the claims to the species in excess of one are written in dependent form or otherwise include all of the limitations of the generic claim. Here, in this application, with regard to Groups I-V, and XIV, Applicant is claiming species limited to human and bovine corneal endothelial cells, BCE-ECM or AG-ECM, and different types of culturing apparatus. This is a reasonable number of species for a generic claim.

Thus, the genus (e.g., independent) claims of the application cannot properly be restricted to the subject matter of the species (e.g., dependent claims). At most, a provisional restriction requirement could be applied to the species claims subject to the non-allowance of the claims generic thereto.

As the restriction requirement does not properly provide for the examination of the genus claims, it is improper and should be withdrawn for this reason alone.

B. No Serious Burden

Furthermore, examination of the patent application would be most expeditious by examining, at least, pending claims of Groups I-V, and XIV together. As Section 803 of the MPEP states,

> If the search and examination of an entire application can be made without serious burden, the Examiner must examine it on the merits, even though it includes claims to distinct and/or independent inventions.

The restriction requirement is improper because the Examiner has not shown that a search and examination of at least, pending claims of Groups I-V, and XIV together would cause a serious burden, as required by the proper restriction practice. In fact, a serious burden would arise only if examination of the patent application were restricted to one of the claim groups. Filing additional patent applications containing the non-elected claims would unnecessarily burden (1) the Patent and Trademark Office, since it must assume the additional labor involved in examining at least two separate applications; (2) the public, since it must bear the cost of the additional labor; and (3) Applicant, since Applicant must bear the substantial financial burden and delay associated with prosecution, issuance, and maintenance of multiple patents.

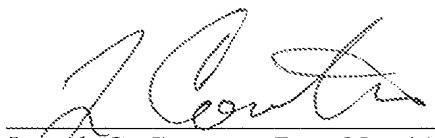
It is clear that for the Examiner to search methods of culturing corneal endothelial cells for transplantation, the search will automatically overlap the species of human and other mammalian corneal endothelial cell references. In addition, since all of this work is *in vitro,* any search of these methods would also overlap and include the species of any ECM used to coat the culture apparatus used grow the cells and the apparatus used in those same references, themselves. Finally, it is clear from the search report, that the literature in this area is quite limited, and as such, a proper search of Groups I-V, and XIV, and the species identified by the Office, would not unduly burden the Office.

As the Office has shown no unnecessary burden on the Patent and Trademark Office that would be caused by examining all of the claims together, the restriction requirement is improper and should be withdrawn for this reason.

Conclusion

Applicant respectfully submits that the patent application is in condition for examination on the merits and allowance. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned attorney.

Respectfully submitted,



Joseph G. Contrera, Reg. No. 44,628
LEYDIG, VOIT & MAYER
700 Thirteenth Street, N.W., Suite 300
Washington, DC 20005-3960
(202) 737-6770 (telephone)
(202) 737-6776 (facsimile)

Date: January 21, 2011

JGC/jj

J:\Cellular Bioengineering\266604\266604 Response to RR.doc